PDB95

WEIGHT- AND HEALTH-RELATED QUALITY OF LIFE (WRQOL AND HRQOL) WITH CANAGLIFLOZIN (CANA) VERSUS SITAGLIPTIN (SITA) IN SUBJECTS WITH TYPE 2 DIABETES MELLITUS (T2DM) ON BACKGROUND METFORMIN

Traina SB[1], Ho KF[2]

[1]*Janssen Global Services, LLC, Raritan, NJ, USA,* [2]*STAT-TU Inc., Toronto, ON, Canada*

OBJECTIVES: CANA is a sodium glucose co-transporter 2 inhibitor developed for the treatment of T2DM. In a Phase 3 multi-national, randomised, double-blind, placebo- and active-controlled study, CANA improved glycaemia and reduced body weight and systolic blood pressure compared with placebo and SITA in subjects with T2DM on background metformin. Herein we report post-hoc analyses of the HRQoL and WRQoL data. **METHODS:** WRQoL and HRQoL were measured using the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) and the 36-item Short Form (SF-36) at baseline, Week 26, and Week 52; with both instruments, higher scores indicate better quality of life. Data were analysed for CANA 100 (n=368) and 300 mg (n=367), and SITA 100 mg (n=366). Least-squares mean changes were evaluated using ANCOVA models; gender, anti-hyperglycaemic adjustment, baseline score, and treatment as covariates. **RESULTS:** Improvements from baseline to Weeks 26 and 52 were detected for WRQoL total, physical function, and self-esteem scores in the CANA (both doses) and SITA groups (95% CI excludes zero), and for the other WRQoL domains, there was either improvement or no difference. A comparison of CANA 300 mg versus SITA at Week 26 suggests a difference in physical function (p=0.0374). Improvements from baseline to Weeks 26 and 52 were also detected for HRQoL general health scores in the CANA (both doses) and SITA groups (95% CI excludes zero), and for other domains, there was either improvement or no difference. Other HRQoL results suggest possible differences in bodily pain (Week 26, CANA 100 mg vs. SITA, p=0.0518) and the mental component summary score (Week 52, CANA 300 mg vs. SITA, p=0.0908). **CONCLUSIONS:** CANA and SITA were associated with improvements in WRQoL and HRQoL over 1 year in dual therapy. Results suggest that CANA is associated with a greater positive impact on patients versus SITA.

PDB96

ASSESSING THE RELATIONSHIP BETWEEN THE DIABETES HEALTH PROFILE AND DIABETES SPECIFIC CLINICAL INDICATORS: CASE FOR TAILORED THERAPEUTICS

Mulhern B[1], Meadows K[2], Churchman D[3]

[1]*University of Sheffield, Sheffield, UK,* [2]*DHP Research & Consultancy Ltd., Banbury, UK,* [3]*University of Oxford, Oxford, UK*

OBJECTIVES: With the increasing use of patient reported outcome measures in diabetes, it is important to understand which dimensions are most relevant to clinical indicators, and are the most predictive when assessing clinical change over time. This is important as the PROM scores can help inform the development of tailored therapeutics by highlighting the psychosocial functioning and quality of life impacts of different treatments. The aim of this study is to assess the relationship between the Diabetes Health Profile (DHP-18) and diabetes specific clinical variables to investigate how the measure can be used in the assessment of the impacts of different related complications and treatments. **METHODS:** The relationship between the DHP-18 and a number of variables, including diabetes specific and co-morbid health complications and length of time diagnosed were assessed. This was done cross-sectionally and longitudinally using a large dataset of Type 1 and Type 2 people with diabetes (n=1,802) collected in one United Kingdom health authority area. The analysis was carried out using Ordinary Least Squares and Logit regression. **RESULTS:** The Psychological distress domain is significantly associated with eye and foot related complications, and a number of co-morbid conditions including depression. The Barriers to activity domain is significantly associated with eye and foot related complications, duration of diabetes and a range of co-morbid conditions. The Disinhibited eating domain is related to duration of diabetes and co morbid conditions such as bone and lung disease. The number of associated problems was also a key predictive variable. **CONCLUSIONS:** The findings indicate that there is relationship between psychosocial functioning as measured by the DHP-18 and a range of clinical indicators. Tailored therapeutics can be used to change or reduce clinical concerns while also impacting on a patient's psychosocial functioning and quality of life, and the DHP can be used to efficiently measure this.

PDB97

A RELATIONSHIP BETWEEN BODY MASS INDEX AND HEALTH-RELATED QUALITY OF LIFE AMONG KOREANS WITH DIABETES: THE KOREA NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

Lee JY, Lee EK

Sungkyunkwan University, Suwon-si, Gyeonggi-do, South Korea

OBJECTIVES: Little is known about the impact of body mass index (BMI) on health-related quality of life (HRQoL) for diabetics in the Korean population. The aim of this study was to estimate the association between BMI and HRQoL of type 2 diabetic patients in Korea. **METHODS:** This study is a cross-sectional analysis of adults who participated in 4th (2007-2009) and 5th (2010-2011) Korean National Health and Nutritional Examination Survey(total, 42,347 participants). HRQoL was measured by EuroQoL five-dimension (EQ-5D) and its association with BMI was investigated in Korean diabetic patients, especially those who did not have adequate control of blood glucose (HbA1c ≥6.5). Multivariate linear regression was performed at p-value of 0.05 with the use of SAS software, version 9.2. **RESULTS:** Out of 42,347 participants, 9.04% had diagnosed of diabetes. Among 2,726 diabetic patients in Korea, we assessed the association in 1,838 patients (median age 63) whose diabetes was not adequately controlled. We found that BMI was significantly negative associated with HRQoL(-0.0038, p-value <0.001), after adjusting for age, sex, education, income, marital status, smoking status, alcohol, HbA1c, insulin treatment status, oral anti-diabetic drug therapy, history of hypertension/high cholesterol/high triglyceride prevalence, stress level, and depression for more than two weeks. EQ-5D index decreased with rising BMI in Korean diabetic patients with HbA1c ≥6.5(-0.0038, p-value <0.001) **CONCLUSIONS:** BMI was negatively associated with HRQoL based on the multivariate regression analysis among Korean diabetic patients with HbA1c ≥6.5, after adjusting for confounding factors. This finding alerts diabetic patients to the danger of the weight gain as it is related to the lower quality of life.

PDB98

HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH TYPE 1 DIABETES AND IMPAIRED HYPOGLYCAEMIA AWARENESS: THE ROLE OF SENSOR-AUGMENTED INSULIN PUMP THERAPY WITH AUTOMATED INSULIN SUSPENSION

McBride M[1], Eggleston AS[2], Jones T[3], Ly T[3]

[1]*Medtronic Australasia Ltd., North Ryde, NSW, Australia,* [2*]*Medtronic International Ltd., North Ryde, Australia,* [3]*Princess Margaret Hospital for Children, Perth, WA, Australia*

INTRODUCTION: Compared with multiple daily injections, insulin pump therapy (continuous subcutaneous insulin infusion - CSII) improves glucose control in patients with type 1 diabetes mellitus (T1DM). When CSII is combined with continuous glucose monitoring (CGM) with automated low glucose insulin suspension (LGS), exposure to hypoglycaemia is significantly reduced. Patients with impaired hypoglycaemia awareness (IHA) are at increased risk of severe hypoglycaemia, so the benefits of this technology should be evident in patient reported health-related quality of life (HRQoL). **OBJECTIVES:** To compare HRQoL in T1DM patients with IHA treated with CSII alone or CSII with CGM + LGS in this 6 month, prospective, single centre RCT. **METHODS:** T1DM patients with IHA and CSII experience were randomised to either CSII alone (control, n=49) or CSII with CGM + LGS (treatment, n=46). Patients >12 years were included in this analysis (n=64, male 50%, age 23.2 ± 11.9 years, diabetes duration 13.8 ± 9.5 years, CSII duration 4.9 ± 3.6 years, Hypoglycaemia Awareness score 6.2 ± 1.4). Hypoglycaemia Fear survey (HFS) and HRQoL (EQ5D) were analysed using ANCOVA least-squares mean change from baseline to 6 months post-randomisation. **RESULTS:** Enrolled patients were not appreciably impaired at baseline (EQ5D Utility mean +SD 0.96+0.07), but overall gains in treatment group (+0.038) and decrements in control (-0.035) over 6 months produced a significant comparative utility gain for the intervention (LS mean difference 0.073, 95% CI: 0.008-0.139, p=0.028). Although not statistically significant, supporting trends were noted in EQ5D VAS and HFS (Worry subscale). **CONCLUSIONS:** Success of T1DM treatment relies upon effective and compliant self-management, so the patient perspective is relevant when evaluating treatment options and determining the impact on aspects of daily life. This analysis further supports the important role of insulin pump therapy plus CGM with automated LGS in the effective management of T1DM patients with IHA.

PDB100

QUALITY OF LIFE (QOL) AND RESOURCES CONSUMPTION IN INSULIN-DEPENDENT DIABETIC PATIENTS WITH A1CNOW+ AND CONTOUR USB. COMET STUDY

Graefenhain R, Vieta A

Bayer, Barcelona, Spain

OBJECTIVES: To analyse the quality of life in insulin-dependent patients and resource consumption due to poor metabolic control after the standarization of glycated hemoglobin measure with A1CNOW+ and the glycemia measure with CONTOUR USB. **METHODS:** An observational, prospective, multicentre study in patients with diabetes, insulin-dependent, with poor metabolic control has been conducted. Distribution of the ESDQOL questionnaire which contains the domains satisfaction, impact, social /vocational, concern regarding diabetes and degree of perception of QoL at baseline, at 3 and 6 months. The score of the domains and the full questionnaire is measured on a scale 0-100; where lower scores indicate a higher QoL. Also, Visual Analogic Scale was used to assess the patient's own perception of their quality of life. The resource consumption is analysed for urgent attention due to poor metabolic control, the use of resources included are visits to emergency department, income, length of hospital stay and additional consultations. **RESULTS:** The evolution of the domains in satisfaction goes from 35.9 at baseline to 31.5 at 6 months. The impact improves from 27.9 at baseline to 26.0 at 6 months, social/vocational concern 25, 8 to 22.4 as well as concerns related to diabetes from 37.7 to 33, 1. Also the degree of perceived improvement in VAS was 2.1 points. All analysed results were statistically significant. At baseline there were 26 patients (7.9%) who required urgent attention due to poor metabolic control in the previous 3 months versus 9 patients (2.8) who requested urgent attention on data collected at 6 months. **CONCLUSIONS:** CONTOUR USB device to measure glycemia and A1CNow device to measure HbA1C improve the quality of life of patients and reduce the use of resources due to poor control.

PDB101

IMPACT OF NOCTURNAL AND DAYTIME NON-SEVERE HYPOGLYCAEMIC EVENTS ON PEOPLE WITH DIABETES IN SOUTH AFRICA

Snyman J[1], Todorova L[2]

[1]*Agility Global Health Solutions, Centurion, South Africa,* [2]*Novo Nordisk International Operations, Zurich, Switzerland*

OBJECTIVES: Two surveys aimed to understand the impact of nocturnal and daytime non-severe hypoglycaemic events on health care system utilisation and patient quality of life. **METHODS:** People with diabetes from six countries who had experienced a non-severe hypoglycaemic event in the 4 weeks prior to the survey were eligible (n=300/survey). In South Africa, surveys were conducted online. **RESULTS:** In the South African nocturnal (N)/daytime (D) hypoglycaemia cohorts (n=50/survey), 80% and 80% (N/D) had type 2 diabetes; 30%/24% (N/D) were male; mean age 45/43 years (N/D); mean diabetes duration 11.1/9.4 years (N/D); 93/93% (N/D) insulin users. 34/40% (N/D) experienced ≥1 non-severe hypoglycaemia events/week. Most respondents (70/76% [N/D]) were unemployed, which could skew the observed impact of hypoglycaemia on productivity. Both surveys revealed that, following an event, it took 20 min (median) for acute symptoms to disappear and 60 min (median) for the respondent to function at their normal level. After an event, 11/11% (N/D) decreased insulin dose, 14/12% (N/D) modified insulin administration time